AngioDynamics Receives FDA Clearance for The NanoKnife® System for Prostate Tissue Ablation

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LATHAM, N.Y.--(BUSINESS WIRE)--Dec. 9, 2024-- AngioDynamics, Inc. (NASDAQ: ANGO), a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving patient quality of life, today announced it received U.S. Food and Drug Administration (FDA) 510(k) clearance for the NanoKnife System for prostate tissue ablation.

The Company received clearance for the NanoKnife System for prostate tissue ablation following the completion of the pivotal PRESERVE clinical study and submission of results to the FDA in September. The study evaluated the safety and effectiveness of the system for ablating prostate tissue in patients with intermediate-risk prostate cancer (PCa). Conducted in collaboration with the Society of Urologic Oncology Clinical Trials Consortium (SUO-CTC), PRESERVE enrolled 121 patients across 17 clinical sites.

"We are incredibly proud to receive FDA clearance for the NanoKnife System's use in prostate tissue," said Jim Clemmer, President and Chief Executive Officer of AngioDynamics. "This milestone is the first step in recognizing our vision to become the standard, function-preserving treatment for men with prostate tumors. The NanoKnife System minimizes the life-altering complications often associated with traditional treatments by selectively targeting prostate tissue while preserving critical functions. As we expand our global footprint and increase access to our technology, we are launching comprehensive education and awareness campaigns to empower physicians with hands-on training and clinical support while engaging patients through innovative outreach initiatives."

Mr. Clemmer added, "These efforts are designed to accelerate the adoption of the NanoKnife System, redefine the standard of care for prostate health, and deliver treatment outcomes that patients and physicians need. AngioDynamics is committed to driving meaningful impact through this revolutionary technology, providing new hope to patients and improved quality of life."

The PRESERVE clinical study met its primary effectiveness endpoint demonstrating the performance of the NanoKnife System for the ablation of prostate tissue in patients with intermediate-risk PCa. At 12-months post-procedure, 84.0% of men were free from in-field, clinically significant disease. In addition, the study demonstrated strong quality of life outcomes with short-term urinary continence being preserved (96.6% at baseline, 95.4% at 12-months) and the ability to maintain erections sufficient for intercourse only decreasing 9% compared to baseline (80.7% to 71.7%).[1]

The study's results validated the robust safety and clinical efficacy profile of the NanoKnife System, reinforcing findings from more than 32 clinical studies performed around the world involving over 2,600 patients.[1]

Prostate cancer is the second most common cancer in men worldwide, with approximately 1.5 million new cases diagnosed annually.[2] Many of these patients seek alternatives to radical procedures that can lead to significant, long-term urological side effects.[3] The NanoKnife System is the first and only non-thermal, radiation-free, ablation technology designed to treat prostate tissue by using IRE technology, offering patients a minimally invasive option for prostate treatment.

The NanoKnife System delivers an innovative alternative to conventional radical surgery or radiotherapy, which often results in significant dysfunction in urinary continence and erectile potency.[4] With its non-thermal approach, the system is engineered to preserve vital structures inside and outside the prostate, offering patients improved outcomes, reduced recovery times, and enhanced quality of life.[5]

For important risk information, visit https://www.angiodynamics.com/about-us/risk-information/#inano

About the NanoKnife System

The NanoKnife System utilizes Irreversible Electroporation (IRE) technology to effectively destroy targeted cells without the use of thermal energy by delivering high-voltage pulses, creating permanent nanopores within the cell membrane. This stimulus induces an apoptotic-like cellular death in the targeted tissue, resulting in a complete ablation of the targeted tissue.[6] Visit nanoknife.com for full product information.

United States: The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue, including prostate tissue.

Canada: The NanoKnife System is a medical device for cell membrane electroporation. Electroporation is a phenomenon that occurs in cell membranes as cells are exposed to an electrical field of sufficiently high intensity. The electric field acts as a physical stimulus, bringing about alterations in cell membranes that result in increased permeability.

European Union: The NanoKnife System is indicated for the ablation of prostate tissue in patients with intermediate risk prostate cancer.

About AngioDynamics, Inc.

AngioDynamics is a leading and transformative medical technology company focused on restoring healthy blood flow in the body's vascular system, expanding cancer treatment options and improving patient quality of life.

The Company's innovative technologies and devices are chosen by talented physicians in fast-growing healthcare markets to treat unmet patient needs. For more information, visit www.angiodynamics.com.

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[1] Data on file.

[2] https://www.wcrf.org/cancer-trends/prostate-cancer-statistics/

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